DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 8 2003

Dr. Lynne Hamilton
Regulatory Affairs
Randox Laboratories Ltd.
Biochemical Manufacturers
Ardmore, Diamond Road
Crumlin, Co. Antrim
United Kingdom, BT29 4QY

Re: k031608
Trade/Device Name: Liquid Protein Calibrators (for neat sample assays) &
Liquid Protein Calibrators (for diluted sample assays)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: May 19, 2003
Received: June 27, 2003

Dear Dr. Hamilton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K031608 ~~NOT KNOWN~~

Device Name **LIQUID PROTEIN CALIBRATORS (for neat sample assays) &**

LIQUID PROTEIN CALIBRATORS (for diluted sample assays)

Indications For Use :

The Randox Laboratories Limited Liquid Protein Calibrators (for neat sample assays) are liquid calibrators derived from normal human serum obtained from volunteer donors. They have been developed for the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin and Transferrin assays (all neat sample assays). Assignment was performed at Randox Laboratories by immunoturbidimetry with reference to material standardised against appropriate International Reference Preparations. The constituent concentrations of these Calibrators are present at levels 0, 1, 2, 3, 4 and 5. These calibrators also contain α-1-Antitrypsin (AAT) and Rheumatoid Factor (RF) for use in the calibration of AAT and RF assays on the Bayer Advia 1650 analyser only.

The Randox Laboratories Limited Liquid Protein Calibrators (for diluted sample assays) are liquid calibrators derived from normal human serum obtained from volunteer donors. They have been developed for the calibration of α-1-antitrypsin, α-1-acid glycoprotein, IgA, IgG, IgM and Transferrin assays which require sample pre-dilution. Assignment was performed at Randox Laboratories by immunoturbidimetry with reference to material standardised against appropriate International Reference Preparations. The constituent concentrations of these calibrators are present at levels 1, 2, 3, 4 and 5.

The Randox Laboratories Limited Liquid Protein Calibrators, should only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

Concurrence of CDRH, Office of Device Evaluation (ODE)

J Pleeves for J. Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K031608

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)